

## **R E M A R K S**

All amendments and cancellation of claims are made without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG),<sup>1</sup> and without waiving the right to prosecute the cancelled claims (or similar claims) in the future.

In the Final Office Action issued 6/6/07, the Examiner issued several rejections. Each of the rejections is discussed in detail below:

### **I. The Claims Do Not Contain New Matter**

The Examiner rejects Claims 26-27 under 35 U.S.C. 112, first paragraph, as allegedly containing new matter. In particular, the Examiner states "This means that the scope of the claim includes a reagent capable of blocking a C5a receptor wherein said reagent 'comprises' within it said monoclonal antibody." (Office Action, pg. 4). The Applicants respectfully disagree. Nonetheless, in order to further the business interests of the Applicants, and without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG), and without waiving the right to prosecute the cancelled claims (or similar claims) in the future, the Applicants have amended Claim 26 to recite "wherein said reagent is a monoclonal antibody..." As such, the Applicants submit that the claims do not comprise new matter and respectfully request that the rejection be withdrawn.

### **II. The Claims are not Anticipated**

The Examiner rejects Claims 26-27 under 35 U.S.C. 102 (b) as allegedly being anticipated by Morgan et al. (U.S. 5,480,974; hereinafter Morgan). The Applicants respectfully disagree with the rejection. In particular, the Applicants submit that Morgan is not enabled for the treatment of sepsis with a monoclonal antibody to C5aR as the presently claimed invention requires. For example, Morgan does not provide any in vivo experimental data showing efficacy of the described antibodies in the treatment of sepsis. Morgan is primarily focused on the

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<sup>1</sup> 65 Fed. Reg. 54603 (Sept., 8, 2000).

generation and characterization of specific antibodies to C5aR. Morgan provides a long list of diseases, of which sepsis is one. There is no way to predict, based on the teaching in Morgan, that the disclosed antibodies would function in the treatment of sepsis. Thus, The Applicants submit that Morgan does not anticipate the presently claimed invention. Nonetheless, in order to further the business interests of the Applicants, and without acquiescing to any of the Examiner's arguments or rejections, and solely for the purpose of expediting the patent application process in a manner consistent with the PTO's Patent Business Goals (PBG), and without waiving the right to prosecute the cancelled claims (or similar claims) in the future, the Applicants have amended Claim 26 to recite that the monoclonal antibody is administered under conditions such that said subject's survival is increased. Morgan does not teach, predict, suggest or enable such a method. As such, Morgan does not anticipate the presently claimed invention and the rejection should be withdrawn.

### **III. The Claims are Not Obvious**

The Examiner rejects Claims 26-27 under 35 U.S.C. 103 as allegedly being obvious in light of Riedemann et al. (J. Clin. Invest. 110:101 (2002); hereinafter Riedemann) in view of Werfel et al. (J. Immunol. 157:1729 (1996); hereinafter Werfel) or Rothermel et al. (Scand. J. Immunol. 52:401 (2000); hereinafter Rothermal) and Behnke et al. (U.S. 5,573,921; hereinafter Behnke). The Applicants respectfully disagree. The Reidemann reference is a publication of the Applicants own work published within the year before the filing date of the present invention, and therefore, is not prior art. See, e.g., MPEP 2132.01 ("Applicant's disclosure of his or her own work within the year before the application filing date cannot be used against him or her under 35 U.S.C. 102(a)." In re Katz, 687 F.2d 450 (CCPA 1982)). The present application claims priority to U.S. provisional 60/423,759, filed 11/5/02. There were five inventors for the present application: Peter A. Ward, Niels C. Riedemann, Ren-Feng Guo, Vidya J. Sarma, and Markus Huber-Lang. The Riedemann reference issued for publication in July 2002. The Riedemann reference lists thirteen authors: Niels C. Riedemann, Ren-Feng Guo, Thomas A. Neff, Ines J. Laudes, Katie A. Keller, Vidya J. Sarma, Maciej M. Markiewski, Dimitrios Mastellos, Christoph W. Strey, Carl L. Pierson, John D. Lambris, Firas S. Zetoune, and Peter A.

Ward. A 37 C.F.R. §1.132 Declaration from Dr. Peter A. Ward is now provided indicating that 1) Peter A. Ward, Niels C. Riedemann, Ren-Feng Guo, and Vidya J. Sarma are the only listed authors who contributed to the inventive process relating to the present invention; and that 2) Thomas A. Neff, Ines J. Laudes, Katie A. Keller, Maciej M. Markiewski, Dimitrios Mastellos, Christoph W. Strey, Carl L. Pierson, John D. Lambris, Firas S. Zetoune were not involved with the inventive process relating to the present invention, worked under Dr. Ward's supervision and direction, and were listed as co-authors of the publication in order to acknowledge their collaboration in a research program under Dr. Ward's direction. As such, per the MPEP §2132.01, the Riedemann reference is not prior art.

Neither Rothermel, Behnke nor Werfel, alone or in combination, teach all of the elements of the presently claimed invention as required for a prima facie case of obviousness under 35 U.S.C. 103. In particular, neither Werfel, Behnke nor Rothermel, alone or in combination, teach a method of treating sepsis under conditions such that said subjects survival is increased. As such, the Applicants respectfully submit that the Examiner has not demonstrated a prima facie case of obviousness and respectfully request that the rejection be withdrawn.

### **CONCLUSION**

If a telephone interview would aid in the prosecution of this application, the Examiner is encouraged to call the undersigned collect at (618) 218-6900.

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